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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/612,314	07/07/2000	Richard Anthony Godwin Smith	088362/0114	8725

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	612,314	Applicant(s)	SMITH et al
Examiner	SAUNDERS	Group Art Unit	1644

--The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address--

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

Responsive to communication(s) filed on 11/14/01

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

Claim(s) 1-26, 28-32, 34, 37, 39, 41-45, 47-48, 50-52 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) 1-26, 28-32, 34, 37, 39, 41-45, 47-48, 50-52 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892 Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948 Other _____

Office Action Summary

DETAILED ACTION

1. The instant application is in sequence compliance for patent applications containing amino acid sequence disclosures.
2. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
3. Applicant's preliminary Amendment (Paper No. 2), filed on 7/7/00, and Amendment B (Paper No. 9), filed on 10/30/01 are acknowledged.
Claims 27, 33, 35-36, 38, 40, 46 and 49 have been canceled.
Claims 3-8, 10-14, 16, 19, 21-23, 27, 29, 34, 37, 39, 41-42, 44-45, 47-48 and 52 have been amended.
Claims 50-52 have been added.
Claims 1-26, 28-32, 34, 37, 39, 41-45, 47-48, 50-52 are pending.

Election/Restrictions

4. The following is noted:

Independent claim 1, and dependent claims thereof encompass a fusion polypeptide containing a cell specific soluble polypeptide and a membrane specific binding element wherein the soluble polypeptide as recited in claims 8, 23, 18 is:

- A) IL-4 Y124D mutein (B cell specific),
- B) Prourokinase,
- C) Streptokinase,
- D) Tissue-type plasminogen activator,
- E) Reteplase,
- F) Leptin,
- G) Complement inhibitors from complement regulatory proteins, hydrids and muteins thereof
- H) scFv antibody against cytokines,
- I) Protein Kinase C,
- J) Antibodies against CD4,
- K) Antibodies against B7/CD28,
- L) Antibodies against CD3/TCR,
- M) Antibodies against CD11b (CR3),
- N) Interferon- β and derivatives,
- O) CR1 polypeptide fragment, or
- P) Thrombolytic agent, or
- Q) Rabbit anti-human erythrocyte membrane antibody.

Wherein the membrane binding element as recited in claims 8-11 is:

- A) Fatty acid derivative from aliphatic acyl groups with about 8 to 18 methylene units,
- B) Fatty acid derivative from long-chain (8 to 18 methylene) aliphatic amines and thiols,
- C) Steroid,
- D) Farnesyl derivatives,
- F) Basic amino acid sequence from DGPKKKKKSPSKSSG,
- G) Basic amino acid sequence from GSSKSPSKKKKKPGD,
- H) Basic amino acid sequence from SPSNETPKKKKRFSFKKSG,
- I) Basic amino acid sequence from DGPKKKKKSPSKSSK,

- J) Basic amino acid sequence from SKDGKKKKKS GTK,
- K) Integral membrane protein from GRGDSP,
- L) Integral membrane protein from DGPSEILRGDFSS,
- M) Integral membrane protein from GNEQSFRVDLRTLLRYA,
- N) Integral membrane protein from GFRLLLKV,
- O) Integral membrane protein from SAAPSSGFRILLLVK,
- P) Integral membrane protein from AAPSVIGFRILLKVAG or
- Q) The carbohydrate ligand Sialyl Lewis^x.

These fusion proteins are unique products. They differ with respect to their structures, molecular composition, target specificity and mode of action; a person of ordinary skill in the art would not envision one in view of the other. Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is a fatty acid derivative from aliphatic acyl group about 1-18 methylene unit, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.
- II. Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is a fatty acid derivative from long-chain (8-18 methylene) aliphatic amines and thiols, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

- III. Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is a fatty acid derivative from steroid, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.
- IV. Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is a fatty acid derivative from farnesyl derivatives, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.
- V. Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is a basic amino acid sequence consisting of DGPKKKKKSPSKSSG, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.
- VI. Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is a basic amino acid sequence consisting of GSSKSPSKKKKPGD, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.
- VII. Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is a basic amino acid sequence consisting of SPSNETPKKKKKRFSFKKSG, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.
- VIII. Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is a basic amino acid sequence consisting of DGPKKKKKSPSKSSK, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.
- IX. Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is a basic amino acid sequence consisting of SKDGKKKKKSKTK, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.
- X. Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is a ligand of known integral membrane proteins consisting of GRGDSP, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

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XI. Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is a ligand of known integral membrane proteins consisting of DGPSEILRGDFSS, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

XII. Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is a ligand of known integral membrane proteins consisting of GNEQSFRVSDLRTLLRYA, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

XIII. Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is a ligand of known integral membrane proteins consisting of GFRILLKV, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

XIV ~~XV~~ Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is a ligand of known integral membrane proteins consisting of SAAPSSGFRILLKV, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

XV ~~XV~~ Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is a ligand of known integral membrane proteins consisting of AAPSVIGFRILLKVAG, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

XVI ~~XL~~ *XVI* Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is a ligand of known integral membrane proteins consisting of the carbohydrate ligand Sialyl Lewis, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

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~~XVII~~ ~~XIII~~ Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is IL-4 Y124D mutein, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

~~XVII~~ ~~XIII~~ Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is prourokinase, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

~~XIX~~ ~~XIV~~ Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is streptokinase, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

~~XXI~~ ~~XXV~~ Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is tissue-type plasminogen activator, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

~~XXII~~ ~~XXXI~~ ~~XXI~~ Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is reteplase, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

~~XXII~~ ~~XVII~~ ~~XXII~~ Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is leptin, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

~~XXIII~~ ~~XVIII~~ ~~XXIII~~ Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is complement inhibitor from complement regulatory proteins and hybrids, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

~~XIV~~ ~~XIX~~ ~~XIV~~ Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is sc Fv antibody against cytokines, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

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~~XXV~~ Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is sc Fv antibody against Protein C, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

~~XXVI~~ Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is sc Fv antibody against CD4, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

~~XXVII~~ ~~XXVII~~ Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is sc Fv antibody against B7/CD28, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

~~XXVIII~~ ~~XXVIII~~ Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is sc Fv antibody against CD3/TCR, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

~~XXIV~~ ~~XXIV~~ Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is sc Fv antibody against CD11b(CR3), and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

~~XXV~~ ~~XXV~~ Claims 1-24, 26, 28, 37, 41, 44, 47 and 50, drawn to soluble derivative of a soluble polypeptide derivative with membrane binding elements wherein the membrane binding element is sc Fv antibody against interferon- β and derivatives, and pharmaceutical composition of said polypeptide classified in Class 530, subclass 350.

~~XXVI~~ ~~XXVI~~ Claims 25, drawn to a process for preparing a derivative, which comprises expressing DNA encoding a polypeptide in a recombinant host cell, recovering the product, and post translationally modifying the polypeptide product to introduce membrane binding elements, classified in Class 530, subclass 402.

~~XXVII~~ ~~XXVII~~ Claims 29-31, drawn to DNA encoding polypeptide, vector, host cells, encoding polypeptides classified in Class 536, subclasses 23.1 and 24.1, and Class 435, subclass 252.3.

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~~XXXIII~~ ~~XXXIV~~ ~~XXXVIII~~ Claims 32, 34 and 52 drawn to peptide membrane binding elements, classified in class 530, subclass 300.

~~XXXIV~~ ~~XXXIX~~ Claim 39, drawn to a method of treatment of disorders amenable to treatment by a soluble derivative of soluble peptide, classified in Class 514, subclass 2.

~~XXXV~~ ~~XXX~~ Claim 42-43, drawn to a method of treating a disease or disorder associated with inflammation or inappropriate complement activation using a soluble complement inhibitor, classified in Class 514, subclass 2.

~~XXXVI~~ ~~XXXI~~ Claim 45, drawn to a method of treating a disease or disorder associated with inflammation or inappropriate complement activation using a soluble CR1 polypeptide derivative, classified in Class 514, subclass 2.

~~XXXVII~~ ~~XXXII~~ Claim 48 and 51 drawn to a method of treating thrombotic disorders with a derivative of thrombolytic agent, classified in Class 514, subclass 2.

The inventions are distinct, each from the other because:

The fusion proteins and/or conjugates of Groups I-XXV are unique products. They differ with respect to their structures, molecular composition, target specificity and mode of action; a person of ordinary skill in the art would not envision one in view of the other. The different recited sequences would require different sequence data base searches. The different membrane binding elements of the various groups (e.g. various enzymes, antibodies, interleukins, peptides, and lipids) would require different searches in the US patent classifications and different subject matter searches in data bases. A teaching of the use of one of these unique products of Groups I-XXV in treating one of the diseases encompassed by Groups XXIX-XXXII need not suggest the use of the same or a different product in treating one of the other diseases. Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

Inventions XXVI and I-XXV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as

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claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide products to be modified can be obtained by means other than their expression in a recombinant host cell – e.g. enzymes can be isolated from natural sources, antibodies can be obtained from hybridoma cells.

Inventions I-XXV and XXVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, polypeptides and DNA polymers, have no common core structure and have different properties and uses.

Inventions I-XXV and XXVIII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the particular Markush group members recited in claim 32 of Group XXXVIII are not recited in any of the claims of Groups I-XXV. The subcombination has a separate utility such as in the derivatisation of carbohydrates so that the carbohydrates can be anchored to artificial membranes (e.g. liposomes).

Inventions I-XXV/XXVIII and XXIX-XXXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the products can be used in processes other than in therapy – e.g. they can be inserted into membranes to be used in a membrane based immunoassay, they can be used in vitro to isolated various cells from a heterogeneous cell population.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following distinct species of the claimed Inventions of Groups IV-VII as disclosed in the specification on page 23-24 wherein the neurological disease or disorder involving complement is:

- A) Multiple sclerosis,
- B) Stroke,
- C) Guillain Barre Syndrome,
- D) Traumatic brain injury,
- E) Parkinson's disease,
- F) Allergic encephalitis, or
- G) Alzheimer's disease.

Wherein disorder of Inappropriate Complement Activation is:

- A) Heamodialysis complications,
- B) Hyperacute allograft rejection,
- C) Xenograft rejection,
- D) Corneal graft rejection,
- E) Interleukin-2 induced toxicity during IL-2 therapy, or
- F) Paroxysmal nocturnal haemoglobinuria.

Wherein inflammatory disorder is:

- A) Crohn's disease,

- B) Adult respiratory distress syndrome,
- C) Thermal injury including burns or frostbite,
- D) Uveitis,
- E) Psoriasis,
- F) Asthma, or
- G) Acute pancreatitis.

Wherein Post-Ischemic Reperfusion Condition is:

- A) Myocardial infarction,
- B) Balloon angioplasty,
- C) Atherosclerosis (cholesterol-induced) and restenosis,
- D) Hypertension,
- E) Post-pump syndrome in Cardiopulmonary bypass or renal haemodialysis,
- F) Renal ischemia, or
- G) Intestinal ischemia.

These species are distinct because the specific diseases differ with respect to their etiologies, and therapeutic endpoints. A treatment of one such disease would not necessarily suggest a treatment of one of the others.

Irrespective of whichever group applicant may elect, applicant is further required under 35 U.S.C. 121:

To elect a specific disease or disorders as recited in claims 39, 42, 45 and 48, to be treated if Group XXIX, Group XXX, Group XXXI, or Group XXXII is elected.

7. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 8, 9, 11, 12, 13, 15, 16, 17, 21, 22, 24 are generic.
8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
10. A telephone call to request an oral election was not made due to the complexity of the restriction.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD, whose telephone number is (703) 308-3976. The examiner can normally be reached Monday through Friday from 8:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.
12. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-4315, for a response to a restriction requirement.

Typed 3/25/02, DAS

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
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